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January 22, 1998

Ms. Magalie Roman Salas
Secretary
Federal Communications Commission
Room 2222, Mail Stop 1170
1919 M Street, N.W.
Washington, DC 20554

Re: RM- 9157 - *Ex Parte*

Dear Ms. Salas:

On January 21, 1998, Steve Goedeke, Engineering Manager for Medtronic, and I made an *ex parte* presentation on behalf of Medtronic, Inc., to Paul Misener, Chief of Staff for Commissioner Furchtgott-Roth, concerning the Petition for Rule Making referenced above, which was filed by Medtronic. In the presentation we explained why the public interest would be served by the Commission's initiation of a notice of proposed rule making in response to the petition. Copies of the materials supplied during our presentation are enclosed.

Please contact me if there is any question concerning this matter.

Sincerely,

David E. Hilliard

David E. Hilliard
Counsel for Medtronic, Inc.

cc: Paul Misener, Esq. (w/ encl.)
Enclosures: RM- 9157 Background Materials

The Medical Implant Communications Service (MICS)

- **On July 28, 1997, Medtronic filed its petition for rule making (RM-9157) asking the Commission to create the Medical Implant Communications Service as a new ultra low power (25 microwatt) personal radio service under Part 95 of the Rules without individual station licenses.**
- **MICS would provide for high capacity (100 kbs) data links in the 402 - 405 MHz band between implanted medical devices such as cardiac pacemakers and programmer/controller units for the rapid exchange of data for medical implant device adjustment and diagnosis of patient conditions.**
- **MICS will:**
  - **bring about beneficial changes in the surgical implantation of medical devices by removing communications equipment from the sterile field by operating with a range of 2 meters vs. the 8 centimeter range of current systems;**
  - **achieve a 40 fold increase in the speed of data communications involving medical implant devices to provide greater patient comfort and give physicians needed additional data;**
  - **improve both home health care and in-hospital monitoring;**
  - **open new telemedicine opportunities; and**
  - **increase the efficient use of both patient and physician resources by reducing the time needed for set-up and data exchange.**

The Medical Implant Communications Service (MICS)

Additional background:

- **RM-9157 appeared on public notice and drew only support.**
- **The 402-405 MHz band can support MICS operations worldwide as a secondary mobile application in spectrum allocated primarily for use by meteorological aids such as transmitters used with weather balloons.**
- **For nearly three years, Medtronic has engaged in dialog with federal spectrum users in order to determine the compatibility of MICS operations with meteorological aids. This effort has resulted in compatibility studies in conjunction with NOAA, the World Meteorological Organization and the ITU to examine how MICS may operate without causing interference to meteorological aids or receiving unacceptable interference from such operations.**
- **MICS is not a replacement for current low power medical telemetry systems. MICS will serve different applications. A need will still exist for 5 to 20 milliwatt systems of the sort now authorized under Part 90 of the Rules and 100 milliwatt systems authorized under the Part 95 Low Power Radio Service.**
- **With revenues of more than 2.5 billion dollars, Medtronic, Inc., based in Minneapolis, Minnesota, is the world's leading manufacturer of cardiac pacemakers, defibrillators and neurological devices. More than one million patients benefited last year from Medtronic technology.**

For information about MICS, please contact:
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MEDTRONIC January 1998

Summary

Medtronic, Inc., of Minneapolis, Minnesota, a world leader in the development of medical implant devices, urges the Commission to issue a notice of proposed rule making calling for the creation of the Medical Implant Communications Service (MICS) under Part 95 of the Rules in the 402 - 405 MHz band. MICS operations would provide for the transmission of data to and from implanted medical devices such as cardiac pacemakers and defibrillators via high speed (100 kbps or more) short-range ultra low power (25 microwatts) wireless links. MICS systems would replace the cumbersome slow speed inductive coupling technology now used.

MICS operations would increase patient comfort and safety while reducing the cost of medical treatment. Conservative estimates of the cost savings run into multiple millions of dollars per year. Patients would run lower risks of infection during the implantation of medical devices. Physicians would be able to obtain vast amounts of data useful for diagnostic and therapeutic purposes. MICS also would aid in the development of new telemedicine applications.

MICS would be licensed by rule without individual station licenses. It would operate on a secondary basis to stations in the Meteorological Aids ("Metaids") Services. The proposed operations have been examined in both U.S. and international forums and found to be compatible with Metaids operations, if conducted under the limitations proposed herein. Use of a portion of the 401.000- 406.000 MHz Metaids band for MICS would set the stage for similar compatible uses around the world because of the international secondary mobile allocation in the Metaids band within all three ITU Regions.

The following figures illustrate the operation of MICS systems and contrast that operation with the methods currently used to communicate with medical implant devices.

At Device Implant

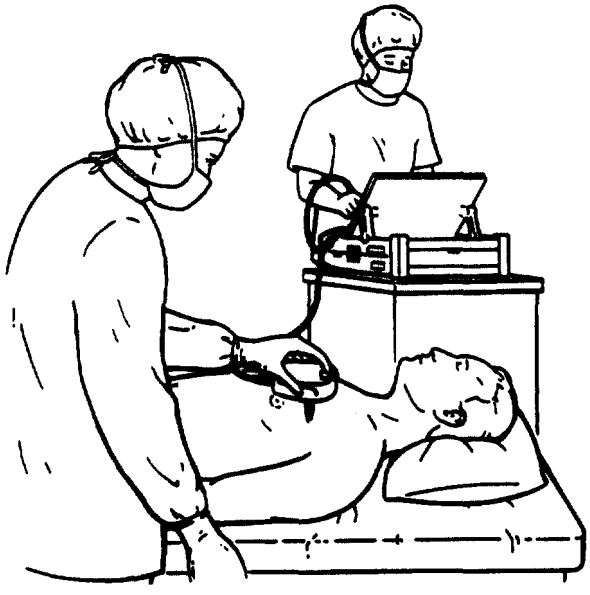

Figure 1A

With the current system: The physician must precisely place the programming head directly over the open incision into which the device has just been placed, which increases the risk of infection. During communication, the programming head must not move, making it necessary for the programmer operator to describe the display to the physician. If the patient moves, the communication link can be broken during the transmission of vital data. Finally, the cord between the patient and the programmer can literally be a stumbling block, limiting the mobility of medical personnel and equipment.

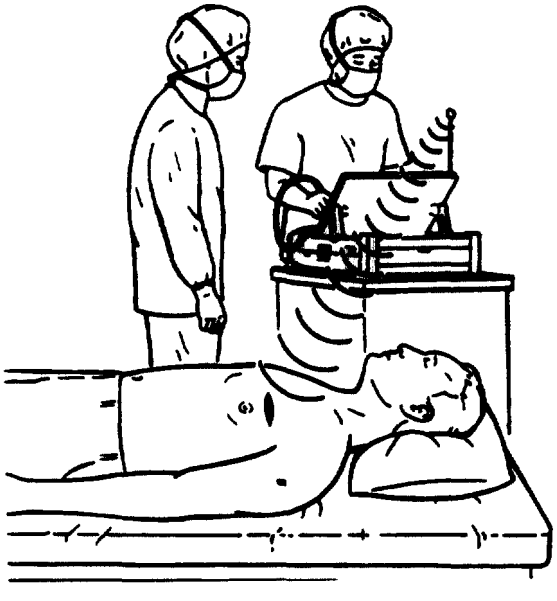

Figure 1B

With MICS: The physician can leave the sterile field and view the implanted device's information in real time. Eliminating the programming head reduces the risk of infection and the problems associated with the cord. Patient movement during the procedure has no impact on communication.

At Device Follow-up

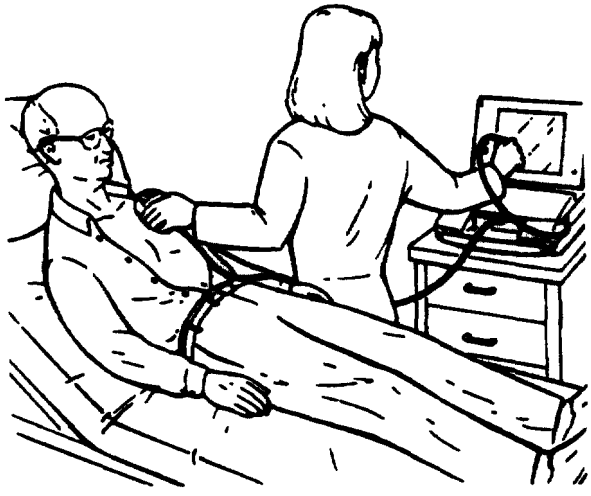

Figure 2A

With the current system: Patients return to their physician on a regular basis (typically the day after implant and then every 6 to 12 months) to have their device's performance evaluated. Establishing communication with the device often requires the patient to disrobe so the device can be found visually and tactually (a result of the current system's very small functional volume). This procedure can be painful, because the area of the incision may be quite tender. During communication, programming head position must be precisely maintained, precluding the physician from performing other duties.

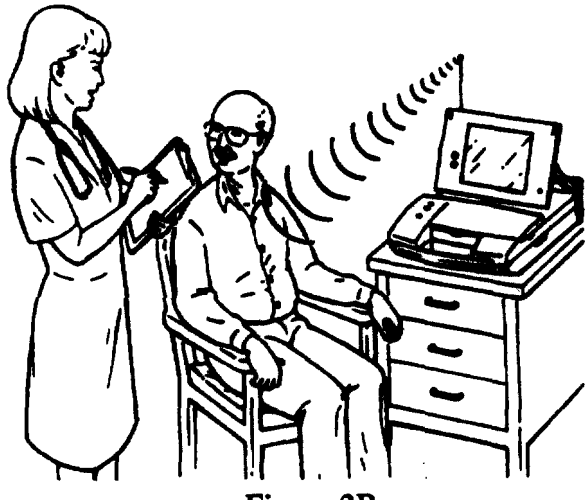

Figure 2B

With MICS: Communication occurs "hands-off," allowing the physician to work with the patient or perform other tasks during device interrogation. In cases where a significant amount of data needs to be recovered, the transaction can occur without medical personnel in attendance. Additionally, there is no need for the patients to disrobe or have their "personal space" violated.

In-Home Monitoring

Figure 3A

With the current system: The current system is too difficult for patients to operate, preventing the wide deployment of home monitoring. Patients are often intimidated by technology or forget to use the system. Additionally, the size and weight of the programming head make it very difficult for a patient to establish and maintain the link. The resulting data are often suspect, resulting in the need for additional transmissions and unnecessary office visits.

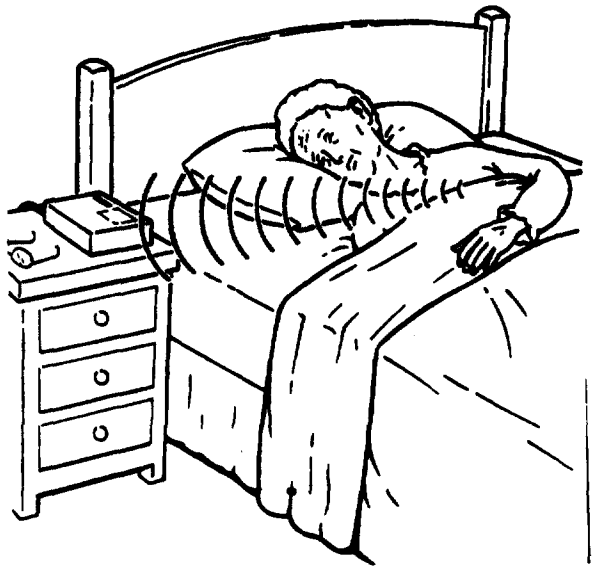

Figure 3B

With MICS: Home monitoring will become a convenient and inexpensive way to care for patients. With this capability, device and patient status can be monitored automatically by a bedside device and the data transmitted to the physician, which will shorten hospital stays as well as reduce clinic and hospital visits. Clearly this will reduce the cost of care and improve the patient's quality of life.

In-hospital Monitoring

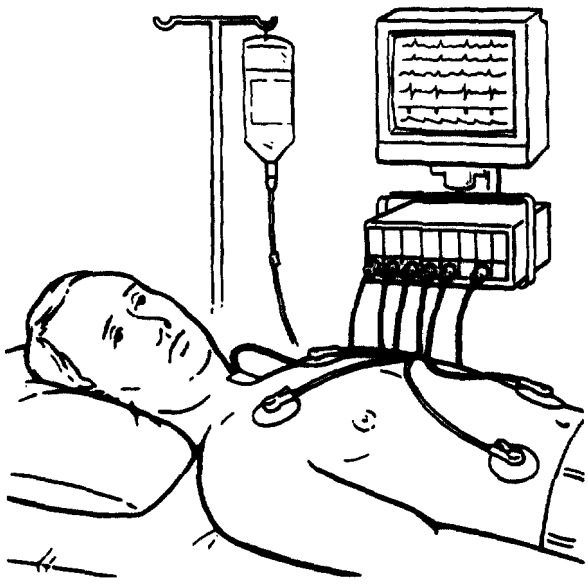

Figure 4A

With the current system: Patients with congestive heart failure and similar diseases frequently return to the cardiac care unit (CCU) as their disease progresses. In the CCU, patients repeatedly undergo dangerous and expensive catheterizations. These catheters measure physiological parameters, such as cardiac output, and are used in conjunction with surface electrodes. These electrodes cause contusions and infections.

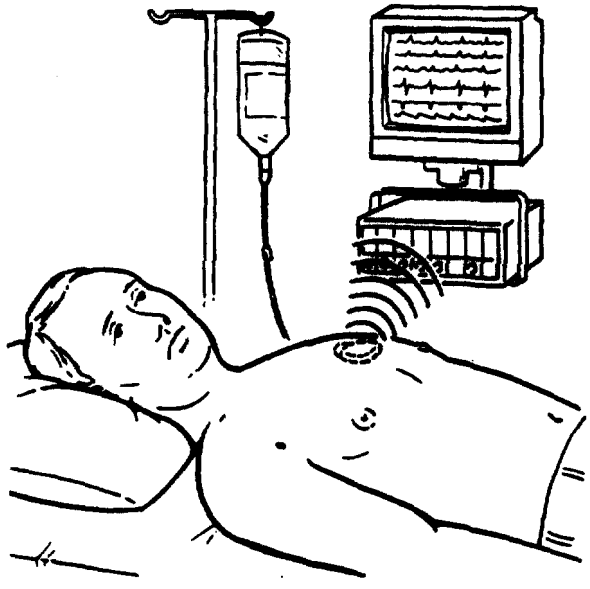

Figure 4B

With MICS: Implantable hemodynamic monitors measure physiologic parameters from within the body. These devices are inserted under the skin and the incision is closed, reducing the potential for complications. Physicians have real time access to parameters whenever the device is activated, which significantly reduces health care costs. In addition to using the devices in the hospital, the same devices can be used for home monitoring, which allows for better control of drug dosages, reducing re-admissions to the hospital. Wireless links to implantable monitors will provide a safer, cheaper, less invasive way to diagnose and manage patient condition.